**MEDI-CAL DRUG USE REVIEW BOARD**
**MEETING MINUTES**
**Tuesday, February 14, 2006**
**10:00 a.m. to Noon**

**Location:** Department of Health Services
1501 Capitol Avenue, Room 71.1203
Sacramento, CA 95814

| Topic | Discussion |
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| **1) CALL TO ORDER** | Meeting was called to order by Dr. McBride<br>Members present: Janeen McBride, Andrew Wong, Ross Miller, Marilyn Stebbins, Tim Albertson, Kenneth Schell, Art Whitney<br>Members absent: Craig Jones, Stephen Stahl, Patrick Finley, Robert Mowers |
| **2) APPROVAL OF LAST MINUTES** | Dr. McBride moved to approve the minutes from the November 8, 2005, Board meeting. Dr. Wong requested several corrections to the minutes: regarding his Rheumatoid Arthritis Study, delete the second "2.", correct "DMAARDs' to "DMARDs", and correct the spelling of the word "inflammatory". In the Summary of Action Items, under 4(d), change "they" to "there". Minutes unanimously approved as amended. |
| **3) CDHS COMMENTS** | A. Dr. Lisa Ashton, California Department of Health Services (CDHS) announced the participation of another State Department and other CDHS Divisions who will participate in Drug Use Review (DUR) Board meetings:<br><br>1. Department of General Services (DGS) currently purchases drugs for four Departments (mental health, juvenile halls, etc); DGS will be working with CDHS on procurements.<br><br>2. Medi-Cal Managed Care Division.<br><br>3. Audits and Investigations (A&I) were unable to attend this DUR Board meeting because of a meeting conflict. A&I will be working with the Medi-Cal DUR program to fulfill the federal requirement for DUR programs to identify issues related to fraud and abuse of medications. A&I has the ability to meet with providers face-to-face and conduct on-site audits. In addition, A&I has an agreement with the regional Medicare office to exchange data.<br><br>4. Medi-Cal Drug Advisory Committee (MCDAC) –members will participate in DUR meetings in order to coordinate DUR program initiatives with drug reviews.<br><br>B. Dr. Ashton provided updates regarding Medicare Part D<br><br>1. In December 2005, providers and patients were encouraged to refill prescriptions with up to 100-day supplies.<br><br>2. The Legislature initiated legislation to allow the Medi-Cal program to pay for Medicare Part D covered drugs because of difficulties some Medicare/Medi-Cal beneficiaries were having obtaining needed medications. On January 12, 2006, the Governor signed the legislation. This allowed Medi-Cal to be the payor of last resort and dispense emergency prescriptions to Medicare Part D beneficiaries who were unable to obtain them under certain circumstances. The original end-date of the emergency dispensing program was February 11 but it has been extended through March 17, 2006. The Governor has the discretion to extend the program.<br><br>3. DUR will be looking at the impact of the emergency dispensing on utilization. A&I will help target claims where Medi-Cal was not the payor of last resort, however there is no current mechanism to enforce this. Dr. Whitney stated that the CMS website |

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| | indicates that Medi-Cal should be billed for Medicare co-payments. Mr. Patrick Robinson, CDHS, clarified that most beneficiaries in long-term care facilities should not have co-pays but were erroneously being billed co-pays by the Part D plans, and it is correct to bill Medi-Cal in these cases.<br><br>4. Mr. Robinson provided an update on data exchange with the Medicare Prescription Drug Plans (PDPs). CDHS is working on data exchange with the PDPs. Currently, 5 out of the 7 PDP providers for California's duals have signed up to exchange data with CDHS. Two PDPs did not sign up presumably due to logistics and time restraints. CDHS sent 6 months of prescription history to the 5 PDPs in late December. Since December, there has been no additional data exchange.<br><br>5. The Board requested clarification as to what is covered by Medicare Part D and what is not. Dr. Wong brought up the drug methotrexate. Dr. Wong uses this medication for some of his arthritis patients. Part B will pay for methotrexate if it is used for cancer but will not pay if the drug is used for arthritis. |
| **4) CalMEND UPDATE** | A. Dr. Barry Handon, CDHS, presented an update on the California Mental Health Disease Management (CalMEND) program.<br><br>1. The committee is working closely with mental health stakeholders to determine how to regulate quality of care based on a common nationwide model (e.g. algorithms and projects in Texas, New York, and Minnesota).<br><br>2. CalMEND is taking a client and family centered approach to ensure the best delivery of care to persons with mental health disorders.<br><br>3. CalMEND has received several million dollars in funding over 3 to 4 years for expansion. A full-time pharmacist with psychopharmacology expertise, plus six additional staff members will be hired. For more information, contact Dr. Handon at bhandon@dhs.ca.gov.<br><br>4. Dr. Albertson inquired about antipsychotic drugs on PDP formularies and whether Medi-Cal had any input on the formularies. Dr. Handon informed the Board that Medi-Cal had no input on the coverage of any drugs on any of the PDP formularies. |
| **5) DISCUSSION OF ONGOING PROJECTS** | A. Atypical Antipsychotic Utilization<br><br>1. Dr. Ashton briefly discussed a sample report that was provided to the CalMEND Practice Management Committee on February 3, 2006. The report is for example purposes and is only meant to be used as a starting point to determine what types of analysis and reports would be useful to make meaningful decisions on medication policy. The analysis represents a ten percent Medi-Cal FFS population for the time period of October 1, 2004 through September 30, 2005. The "before" data represents all beneficiaries with an antipsychotic claim while the "after" data excludes those beneficiaries who are also Medicare eligible. The reports are provided to the DUR Board for comments and input. Dr. Schell provided that emergency room utilization with diagnosis information would be useful.<br><br>2. Antipsychotic Polypharmacy Letter to Long-Term Care (LTC) Providers. Dr. Ashton stated that the Top 10 LTC pharmacies with polypharmacy likely changed since January 1, 2006; therefore, the data needs to be cut with more current utilization. Dr. Miller stated that the letter should place responsibility for patient follow-up on the prescriber as well as the pharmacy. Dr. Wong requested the following language changes: substitute "misidentified" with "misclassified", and substitute "participation" with "collaboration."<br><br>B. Acetaminophen (APAP) Toxicity Monitoring<br><br>1. Mr. Vic Walker, California Department of Health Services (CDHS), presented this item as a follow up to the APAP report presented at the November Board meeting. The |

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| | new analysis looked at plain APAP and APAP in combination with other drugs, controlled versus non-controlled, and cumulative doses of 4, 8, 12, and 16 grams APAP per day.<br><br>2. This analysis was done using a 1 year period (October 1, 2004 through September 30, 2005). There were 61 patients receiving high dose APAP for more than 100 days with renal or hepatic disease, and one person received as much as 4.4 kilograms of APAP in one year.<br><br>3. Board Comments:<br><br>a) Dr. McBride asked if it is possible to limit how much APAP is dispensed per claim via a hard edit on cumulative daily dosages above 8 grams/day. Maureen Tooker (CDHS) replied that this would require major system changes to tables and is an item for the formulary re-write project.<br><br>b) Dr. Miller requested that the 61 beneficiaries with renal/hepatic disease be further reviewed, also looking at the prescribers. Dr Miller also suggested that information on the average number of pharmacies and average number of prescribers by patient be added to the report.<br><br>c) Dr. Albertson requested that the information provided in the APAP toxicity report be disseminated via a provider bulletin.<br><br>C. Update on Board members conducting studies<br><br>1. Two projects have gained approval from the Committee for Protection of Human Subjects:<br><br>a) Dr. Albertson's and Dr. Stebbins' asthma study.<br>b) Dr. Wong's rheumatoid arthritis study.<br><br>2. Additional ongoing studies:<br><br>a) Dr. Finley's antidepressants in children and adolescents study.<br>b) Dr. Albertson's acetaminophen toxicity study. |
| **6) ProDUR** | A. Prospective DUR Project<br><br>1. ProDUR Impact Improvement Subcommittee - the objective is to make the alerts more clinically useful while complying with OBRA requirements. Prior information provided to the Board included the target drug list, and new target drug list guiding principles (which have not yet been applied). CDHS requested feedback on the new guiding principles and target drug list, and requested volunteers for the ProDUR Subcommittee. Dr. Schell and Dr. McBride volunteered to be members of the subcommittee. All members agreed with the guiding principles. Dr. Schell wanted clinical relevance to be included in the guiding principles and Dr. McBride wishes to add cost as a factor in guiding principle number 3.<br><br>2. Review of Early Refill (ER) Alerts - the top 100 drugs receiving the ER alert were presented. Currently all drugs are screened for ER, and the ER alert is set when there is more than 75% of days supply remaining on the prior prescription filled. Questions to be addressed by subcommittee will be: (1) since preventing early refills is not enforced, can any drugs be carved out? (2) Medicare Part D will change the landscape of the actual ER alert numbers and drugs; therefore new criteria will have to be developed to clean up the ER alert. A Board Member requested for future reports to include information on top pharmacies by ER Alert. |
| **7) EDUCATIONAL BULLETINS** | A. Currently, there are two methods of distributing the DUR educational articles: (1) Articles are included in hard copies of provider manual update mailings (2) Articles are available electronically on the DUR website.<br><br>B. A hard copy of the provider manual update mailing was displayed to the Board for |

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| | reference. Dr. Albertson stated that the current distribution methods in no way constitute providing education, and he recommended a one-page electronic summary should be disseminated. Dr. Ashton stated that CDHS is looking for better methods to get out information quicker and more clearly. A Board Member inquired about electronic notification of bulletins. However, it was unclear which bulletins the Board Member was referring to. More information about distribution methods to be gathered for next meeting. |
| **8) UTILIZATION REPORTS** | A. Quarterly Report for DUR Board review:<br><br>1. Dr. Miller noted that the June 2004 spike in spending due to changes in payment reporting was inconclusive. Therefore he requested that subsequent quarterly reports begin reporting from July 2004 forward (or an 18 month rolling period).<br><br>2. Given the new landscape in utilization of drugs post implementation of Medicare Part D, future studies and DUR targets should focus on drugs used in the young age populations.<br><br>B. Generic Drug Usage Report 2004 (Analysis of Express Scripts Research Study Findings)<br><br>1. The Express Scripts (ESI) Study estimated generic savings opportunities across six therapy classes for large states such as California, Texas, Florida, etc. For California, this study estimated a potential savings of $1,590,978,627 from the 6 therapy classes studied.<br><br>2. CDHS analysis of generic maximization of the 6 therapeutic categories indicated that calculated savings were less than half of the figures estimated by the ESI Study (without taking into account federal and supplemental rebates). Therefore, additional analysis has been stopped.<br><br>3. Reasons for differences in calculated savings could be:<br><br>a) Top 6 Therapy Classes- the ESI Study used the top 6 drugs for a commercially insured population, which represented 41% of drug spending. The same 6 classes only represented 37% of the Medi-Cal FFS drug spend, with atypical antipsychotics being the class of highest cost.<br>b) Study Population Differences- the Medi-Cal FFS population is demographically different from the ESI populations used such as states with at least 1,500 commercially insured lives.<br>c) Dual Eligibles- in 2004, there was larger utilization by dual eligibles in the Medi-Cal population compared to the ESI population.<br>d) Closed System Model- the ESI Study used Kaiser's closed system as a model for comparison, which is not comparable to Medi-Cal's open system. Dr. Miller pointed out that closed systems such as Kaiser make substitutions such as interchanging lovastatin with the more efficacious statins such as atorvastatin.<br>e) Benefit Design Differences-<br><br>i) Mandatory Generic Substitution- Medi-Cal FFS is not a mandatory generic program, rather there are profitability incentives for pharmacies using generics when possible. In other words, the "spread of profitability" is greater for generic dispensing.<br>ii) Cost Sharing- Medi-Cal FFS does not have a policy of charging tiered co-payments.<br>iii) Therapeutic Substitution- Medi-Cal FFS does not mandate therapeutic substitution or step-therapy, as these methods require prior authorization.<br>iv) Maximum Allowable Ingredient Cost (MAIC) Pricing- The Medi-Cal FFS program does not use this pricing method, which is typical of commercial and managed plans. In 2007, there will be a new ruling on Federal Upper Limit (FUL) pricing which will price generics at 250% of average wholesale price once the second generic product is introduced to market. |
| **9) 2006 CALENDAR** | A. The next three meetings are tentatively scheduled for the following dates:<br>1. May 9, 2006<br>2. September 12, 2006<br>3. November 7, 2006 |

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| **10) PUBLIC AND DUR BOARD COMMENTS** | None |
| **11) DATE OF NEXT DUR BOARD MEETING** | Tentatively scheduled for May 9, 2006. |
| **12) ADJOURNMENT** | The meeting adjourned at 12:05 PM. |

**Summary of Action Items:**

1. **Amend 11/8/05 meeting minutes as identified in Topic 2**

2. **Medicare Part D**
   a) Clarify Part D issues, such as what is covered and what is not, and report findings to the Board.

3. **A Atypical Antipsychotic Utilization**
   a) Additional data on emergency room admissions with psychiatric and non-psychiatric diagnosis codes.
   b) Amend Antipsychotic Polypharmacy Letter to LTC Providers as follows: the letter should be directed toward the prescriber as well as the pharmacy, substitute “misidentified” with “misclassified”, and substitute “participation” with “collaboration”.

4. **APAP Toxicity Monitoring Report**
   a) Board recommendations:
      1. Determine if possible to limit maximum APAP per day (system change).
      2. Further review 61 beneficiaries with renal/hepatic disease. Also look at the prescribers.
      3. Disseminate in a provider bulletin the information provided in the APAP toxicity report.
      4. Report average number of pharmacies and average number of prescribers by patient.

5. **New Target Drug Guiding Principles and ER Alert**
   a) Revise language to reflect high cost and clinical relevance on guiding principles.
   b) Rank pharmacies by highest number of ER alerts.

6. **ProDUR Project**
   a) Review current target drugs against new criteria.
   b) Develop methodology for review of categories.
   c) Set up conference calls with Subcommittee to discuss strategies.

7. **Educational Articles**
   a) For publication, look at distribution of educational articles and determine if there are other ways, particularly electronically, to push out this information.
   b) Sign up Board members to get electronic notification of bulletins.

8. **Quarterly Utilization Report**
   a) Future quarterly reports to report an 18-month rolling period.